Listing of Claims:

Claim 1 (Original) A method for identifying asymptomatic patients who have a likelihood of benefiting from the administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer, said method comprising;

providing a ductal fluid sample from at least one duct of a breast of the patient; and

examining the ductal fluid sample to determine the presence of precancerous or cancerous ductal epithelial cells,

wherein patients determined to have the presence of either precancerous or cancerous ductal epithelial cells are considered likely to benefit from administration of an estrogen acitivity modulator.

Claim 2. (Original) A method as in claim 1, wherein the precancerous ductal epithelial cells comprise cells at a stage selected from the group consisting of ductal hyperplasia, atypical ductal hyperplasia, and low grade ductal carcinoma *in situ* (LG-DCIS).

Claim 3. (Original) A method as in claim 1, wherein the cancerous ductal epithelial cells comprise cells at a stage selected from the group consisting of high grade ductal carcinoma *in situ* (HG-DCIS) and invasive carcinoma.

Claim 4. (Original) A method as in claim 1, wherein providing the ductal fluid sample comprises obtaining the sample from the breast.

Claim 5. (Original) A method as in claim 1, wherein providing the ductal fluid sample comprises receiving a sample which had been previously obtained.

Claim 6. (Original) A method as in claim 1, wherein the fluid was obtained by nipple aspiration of the milk ducts or by ductal lavage of at least one breast milk duct.

Claim 7. (Original) A method as in claim 6, wherein the fluid collected is from a single duct.

Claim 8. (Original) A method as in claim 1, wherein examining the ductal fluid comprises cytological examination of ductal epithelial cells in the sample to determine whether they are precancerous or cancerous.

Claim 9. (Original) A method as in claim 1 [or 8] wherein examining the ductal fluid comprises detection of an estrogen receptor in the ductal epithelial cells.

Claim 10. (Original) A method as in claim 9 wherein examining the ductal fluid comprises detecting the absence of TGF-ß in the ductal fluid.

Claim 11. (Original) A method as in claim 1 [or 8] wherein examining the ductal fluid comprises detection of a change in a level of a marker selected from the group consisting of carcinoma embryonic antigen (CEA), prostate specific antigen (PSA), erb B2 antigen, gross cystic disease fluid protein –15 (GCDFP-15), and lactose dehydrogenase (LDH) in the ductal fluid.

Claim 12. (Original) A method as in claim 1 [or 8] wherein examining the ductal fluid comprises detecting a chromosomal abnormality in the ductal epithelial cells.

Claim 13. (Original) A method as in claim 1, wherein the asymptomatic patients comprise patients in a high risk group for breast cancer selected from the group consisting of patients with a family history of breast cancer, patients of increasing age, patients having at least one high risk parity factor, patients having high risk gene status, patients having at least one

previous breast biopsy, patients having a previous diagnosis of breast cancer, and patients having any other risk factor for breast cancer.

Claim 14. (Original) A method as in claim 1, wherein the asymptomatic patients comprise patients selected from [the] a group [of patients] consisting of patients who are negative in a standard cancer test and patients with inconclusive or ambiguous results from a standard cancer test.

Claim 15. (Original) A method as in claim 1, wherein the estrogen activity modulator comprises a class of agents selected from the group consisting of a selective estrogen receptor modulator (SERM), an estrogen antagonist, and a modulator of estrogen synthesis.

Claim 16. (Original) A method as in claim 1, wherein the estrogen activity modulator comprises a drug in a class selected from the group consisting of tamoxifen, raloxifene, EM 800, droloxifene, ioxdroxifene, RU 39411, RU 58668, ICI 164384, faslodex, soy, a soy isoflavone, a gonadotropin releasing hormone agonist, and an aromatase inhibitor.

Claim 17. (Original) A method as in claim 16, wherein the estrogen activity modulator comprises a soy isoflavone, and the soy isoflavone is genistein or daidzein.

Claim 18. (Original) A method as in claim 16, wherein the estrogen activity modulator comprises an aromatase inhibitor, and the aromatase inhibitor is toremifene.

Claims 19-31. Cancelled.

Claim 32. (Original) A method for identifying patients who have a decreased likelihood of benefiting from the administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer, said method comprising:

providing a ductal fluid sample from a breast of the patient; and

examining the ductal fluid sample to determine the presence of transforming growth factor-ß (TGF-ß), or the absence of estrogen receptor;

wherein the presence of TGF-ß or the absence of estrogen receptor in the ductal fluid sample indicates that the patient is less likely to benefit from the administration of an estrogen activity modulator.

33. (Original) A method as in claim 32, wherein providing the ductal fluid sample comprises receiving a sample which had been previously obtained.

34. (Original) A method as in claim 32, wherein the fluid was obtained by nipple aspiration of the milk ducts or by ductal lavage of at least one breast milk duct.

35. (Original) A method as in claim 32, wherein the patients are receiving an ongoing therapy for risk reduction or treatment of breast cancer.

36. (Original) A method as in claim 35 wherein the therapy comprises administration of an estrogen activity modulator.

37. (Original) A method as in claim 32, wherein the patient has been found to have precancer or cancer of the breast.

38. (Original) A method as in claim 37, wherein the precancer or cancer is determined by examining a ductal fluid sample of the breast of the patient.

39. (Original) A method as in claim 32, wherein the patient has a family history of breast cancer.

Claims 40-44. Cancelled

Claim 45. (Original) A method of monitoring on-going therapy in a patient at risk of or suffering from breast cancer, said method comprising:

comparing a first level of a marker measured in a ductal fluid sample taken at a first time with a second level of the marker measured in a ductal fluid sample taken at a later time.

Claim 46. (Original) A method as in claim 45, wherein the ductal fluid samples are retrieved from the patient by nipple aspiration or ductal lavage of at least one breast milk duct.

Claim 47. (Original) A method as in claim 45, wherein the therapy comprises administration of an estrogen activity modulator.

Claim 48. (Original) A method as in claim 47, wherein the estrogen activity modulator comprises a drug in class selected from the group consisting of a selective estrogen receptor modulator (SERM), an estrogen antagonist, and an inhibitor of estrogen synthesis.

Claim 49. (Original) A method as in claim 45, wherein the therapy is begun before the marker is measured.

Claim 50. (Original) A method as in claim 45, wherein the therapy is begun after the marker is measured.

Claim 51. Original) A method as in claim 45, wherein the marker is measured periodically.

Claim 52. (Original) A method as in claim 49[, 50, or 51] wherein the therapy comprises administration of an estrogen activity modulator.

Claim 53. (Original) A method as in claim 45, wherein the marker is selected from the group consisting of neoplastic ductal epithelial cells, transforming growth factor –ß (TGF- ß),

estrogen receptor, chromosomal abnormality, carcinoma embryonic antigen (CEA), prostate specific antigen (PSA), Erb B2 antigen, gross cystic disease fluid protein –15 (GCDFP-15), and lactose dehydrogenase (LDH).

Claim 54. (Original) A method as in claim 45, wherein the marker is neoplastic ductal epithelial cells at a stage selected from the group consisting of hyperplasia, atypical hyperplasia (ADH), low grade ductal carcinoma *in situ* (LG-DCIS), high grade ductal carcinoma *in situ* (HG-DCIS) and invasive carcinoma.

Claim 55. (Original) A method as in claim 45, wherein comparing comprises determining a change in cellular stage, an increase of a marker, or a decrease of a marker, and further wherein comparing a first marker level and a later marker level can determine whether the patient is better, worse or unchanged.

Claim 56. (Original) A method as in claim 45, wherein the marker is TGF-ß and an increase in TGF-ß indicates that the patient is worse.

Claim 57. (Original) A method as in claim 45, wherein the marker is estrogen receptor and a decrease in presence of estrogen receptor indicates that the patient is worse.

Claim 58. (Original) A method as in claim 54, wherein the marker is neoplastic cells and a change in cellular stage ranging from hyperplasia to invasive carcinoma indicates that the patient is worse.

Claim 59. (Original) A method as in claim 55, further comprising recommending a treatment course selected from the group consisting of stopping the therapy, changing the drug being administered, changing the dosage of the drug being administered, and further monitoring the patient.

Claim 60. (Original) A method for analyzing ductal fluid, said method comprising:

providing a ductal fluid sample from a breast of the patient; and

examining the ductal fluid sample to identify a level or quality of a marker selected from the group consisting of trnasforming growth factor-ß (TGF-ß), estrogen receptor, and chromosomal abnormality.

61. (Original) A method as in claim 60, further comprising examining the ductal fluid sample to identify a level or quality of a second marker.

62. (Original) A method as in claim 61, wherein the second marker is selected from the group consisting of carcinoma embryonic antigen (CEA), prostate specific antigen (PSA), Erb B2 antigen, gross cystic disease fluid protein –15 (GCDFP-15), lactose dehydrogenase (LDH), epidermal growth factor receptor (EGFR), and p53.

63. (Original) A method as in claim 60[, 61, or 62] wherein providing the ductal fluid sample comprises obtaining the sample from the breast.

64. (Original) A method as in claim 60[, 61, or 62] wherein providing the ductal fluid sample comprises receiving a sample which has been previously obtained.

65. (Original) A method as in claim 60[, 61, or 62] wherein the ductal fluid was obtained by nipple aspiration of the milk ducts.

66. (Original) A method as in claim 60[, 61, or 62] wherein the ductal fluid was obtained by ductal lavage of at least one breast milk duct.

67. (Original) A method as in claim 60[, 61, or 62] wherein the ductal fluid was collected from a single duct.

68. (Original) A method as in claim 60[, 61, or 62] wherein examining the ductal fluid further comprises cytological examination of the ductal epithelial cells in the sample.

69. (New) A method as in claim 50 wherein the therapy comprises administration of an estrogen activity modulator.

70. (New) A method as in claim 51 wherein the therapy comprises administration of an estrogen activity modulator.